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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of
Carlos Vonderwalde Freidberg

For: **NON-THROMBOGENIC STENT JACKET**

Serial No.: Not Assigned

Filed: November 17, 2000

Atty. Docket No.: 24079-1071

Examiner: Not Assigned

Group Art Unit: Not Assigned

REQUEST FOR FILING A CONTINUATION APPLICATION UNDER 37 CFR §1.53(b)

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BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a request for filing a continuation application under 37 C.F.R. § 1.53(b), of pending prior application Serial No. 09/156,034, filed September 17, 1998, of Carlos Vonderwalde Freidberg for **NON-THROMBOGENIC STENT JACKET**, which is a continuation-in-part application of application Serial No. 08/935,784, filed September 23, 1997, entitled STENT COVERED WITH HETEROLOGOUS TISSUE, and application Serial No. 09/005,972, filed January 12, 1998, entitled STENT WITH A BIOCOMPATIBLE NON-THROMBOGENIC JACKET, and application Serial No. 09/035,114, filed March 4, 1998, entitled NON-THROMBOGENIC STENT JACKET CONTAINING THERAPEUTIC AGENTS, and application Serial No. 09/053,200, filed April 1, 1998, entitled NON-THROMBOGENIC STENT JACKET, which are incorporated herein in their entirety.

1. Enclosed is a true copy of the prior complete application as filed, including the specification (including claims), drawings, oath or declaration showing the signature or an indication it was signed, and any amendments referred to in the oath or declaration filed to complete the prior application.

2. This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above. With respect to the prior copending U.S. application from which this application claims benefit under 35 U.S.C. § 120, the inventor(s) in this application is (are):

/X/ the same as those named in the prior application.

/__/ less than those named in the prior application and it is requested that the following inventors identified above for the prior application be deleted:

3. /X/ The filing fees are to be calculated on the claims as filed in the prior application.

Description	Claims	Extra	Rate	Fee Code	Fee
Basic Filing Fee				**201**	$355
Independent Claims	4 - 3 =	1 x	$40 =	**202**	$ 40
Total Claims	31 -20 =	11 x	$9 =	**203**	$ 99

Total Filing Fee.....$494

4. Payment of Filing Fees:

/X/ A check in the amount of $494 is enclosed herewith.

/X/ The Commissioner is authorized to charge any additional fees and to credit any overpayment of fees which may be required under 37 C.F.R. §1.16 and §1.17, to Deposit Account No. 08-1641, referencing Docket No. 24079-1071. **A duplicate copy of this paper is attached.**

5. Please amend the specification by inserting before the first line after the words "This application" -- is a continuation of pending prior application Serial No. 09/156,034, filed September 17, 1998, which is a --.

6. The prior application is assigned of record to:

Diseño y Desarrollo Médico, S.A. de C.V.

7. The power of attorney in the prior application is to: **Edward J. Lynch.**

/X/ The power appears in the original papers in the prior application.

/__/ A Power of Attorney and Revocation of Prior Powers is enclosed.

8. **Please address all future correspondence to:**

Edward J. Lynch
Heller Ehrman White & McAuliffe LLP
525 University Avenue, Suite 1100
Palo Alto, CA 94301-1900

9. Documents enclosed:

/ X / Copy of prior complete application as filed (including the signed Declaration and Power of Attorney);

/ X / Preliminary Amendment;

/ X / Return Receipt Postcard.

Respectfully submitted,

By: _____
Edward J. Lynch
Registration No. 24,422

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of Carlos Vonderwalde Freidberg For: **NON-THROMBOGENIC STENT JACKET** Serial No.: not assigned Filed: herewith Atty. Docket No.: 24079-1071	Examiner: not assigned Group Art Unit: not assigned **PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please amend the above-referenced application as indicated below.

IN THE CLAIMS

Please cancel claims 21-28, 31, 33 and 34, without prejudice.

Please amend claims 1-3, 9-11, 29, 30 and 32 , as follows:

1. (Amended) A stent assembly for maintaining the patency of a body lumen comprising an expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic material, the cylindrical jacket comprising a thinned layer of tissue having a surface formed from removal of an outer layer of the tissue.

2. The stent assembly of claim 1 wherein the cylindrical jacket [is formed of heterologous tissue] comprises a type of heterologous tissue selected from the group consisting of pericardium, aortic leaflet, veins, and arteries, the removed outer layer being the same type of tissue as the thinned layer of tissue.

3. The stent of claim [2] 1, wherein the [heterologous] tissue is selected from the group consisting of bovine pericardium, porcine pericardium, and aortic leaflet, veins and arteries.

9. (Amended) The stent assembly of claim 1 wherein the [stent] cylindrical jacket is disposed within the [cylindrical jacket] stent.

10. (Amended) A method for maintaining the patency of a body lumen comprising the steps of:

a) mounting on a delivery catheter a stent assembly comprising a tubular expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic expandable material, the cylindrical jacket comprising a thinned layer of tissue having a surface formed from removal of an outer layer of the tissue;

b) advancing the delivery catheter through the body lumen until the stent assembly is positioned at a desired location;

c) expanding the stent assembly to anchor it within the [bodily] body lumen; and

d) withdrawing the delivery catheter.

11. (Amended) A cylindrical jacket formed of heterologous tissue configured to fit over a portion of an intraluminal stent, the cylindrical jacket comprising a thinned layer of tissue having a surface formed from removal of an outer layer of the tissue.

29. (Amended) An expandable jacketed stent comprising a metallic tubular member configured to expand from a first circumference [configuration] to a second circumference [configuration], and a jacket formed of [heterologous] tissue [containing a therapeutic or diagnostic agent and having a thickness of about 0.05 mm to about 0.20 mm] on an outer surface of the stent in a wrapped configuration configured to unwrap as the stent expands.

30. (Amended) The jacketed stent of claim 29 wherein the jacket [is on an outer surface of the stent in a folded configuration configured to unfold as the stent expands to the second circumference configuration] has a circumference on the unexpanded stent larger than the first circumference of the stent, and a circumference on the expanded stent about equal to the second circumference of the stent.

32. (Amended) A method of treating a patient, comprising:

a) providing an elongated delivery catheter having an expandable member on a distal extremity thereof;

b) mounting onto the expandable member on the distal extremity of the delivery catheter an expandable stent having first circumference and a second expanded circumference and having a cylindrical jacket formed of biocompatible, non-thrombogenic expandable material on an outer surface of the stent in a wrapped configuration configured to unwrap as the stent expands to the second circumference configuration[, the jacket having a width about equal to the second expanded circumference of the stent];

c) advancing at least the distal extremity of the catheter within a body lumen of the patient until the jacketed stent is disposed at a desired location within the body lumen;

d) expanding the expandable member on the distal extremity of the catheter to expand the jacketed stent mounted thereon and unwrap the jacket as the stent expands, and fix the expanded jacketed stent within the body lumen; and

e) contracting the expanded expandable member so the elongated delivery catheter can be removed from the patient.

Please add new claims 35-44, as follows.

35. The stent assembly of claim 1, wherein the cylindrical jacket has a length less than a length of the stent.

36. The stent assembly of claim 1, wherein the cylindrical jacket has a length greater than a length of the stent, the length of the cylindrical jacket being not more than 5% greater than the length of the stent.

37. The stent assembly of claim 1, wherein the stent is expandable from an unexpanded configuration to an expanded configuration, and wherein the cylindrical jacket has a circumference on the unexpanded stent larger than a circumference of the stent in the unexpanded configuration, and a circumference on the expanded stent about equal to a circumference of the stent in the expanded configuration.

38. The jacketed stent of claim 29 wherein the jacket in the wrapped configuration on the unexpanded stent is wrapped about the stent and at least a section of itself so that multiple layers of jacket are present on at least part of the unexpanded stent.

39. The jacketed stent of claim 38 wherein the jacket is a ribbon spirally wrapped about the unexpanded stent with adjacent turns of the ribbon overlapping.

40. The jacketed stent of claim 38 wherein the jacket has a first edge and a second edge extending the length of the jacket, the first edge overlapping the second edge to form the wrapped configuration the first edge being free to unwrap around the stent upon expansion of the stent.

41. The jacketed stent of claim 38 including at least one securing member releasably fixing the jacket in the wrapped configuration prior to expansion of the stent.

42. The jacket stent of claim 29 wherein the jacket is a thinned layer of tissue having a thickness of about 0.05 mm to about 0.20 mm.

43. The stent assembly of claim 1 wherein the tissue surface is a cut surface formed by removal of the outer layer of tissue by a method selected from the group consisting of peeling and shaving.

44. The stent assembly of claim 43 wherein the cut surface extends along a length of the jacket, so that the jacket has a reduced outer diameter along the length of the jacket .

REMARKS

Applicant has preliminarily amended claim 1 to call for an expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic material, the cylindrical jacket comprising a thinned layer of tissue having a cut surface formed from removal of an outer layer of the tissue. In copending parent application U.S. Serial No. 09/154,034, the Examiner rejected claim 1 calling for a stent assembly having a cylindrical jacket comprising a thinned layer of heterologous tissue having a cut surface formed from removal of an outer layer of the tissue, the removed outer layer being the same type of tissue as the thinned layer of tissue, as anticipated by Rawlings et al (WO 97/12563, stating that the acellular matrix of Rawlings et al. is thinned to the extent required by the claims because extraction and removal of tissue cells on at least the outer surface is done via surfactants and other agents. However, Rawlings et al. does not disclose or suggest a

jacket for a stent comprising a thinned layer of tissue having a surface formed by removal of an outer layer of the tissue. In contrast, Rawlings et al., discloses the a stent jacket formed from extracellular matrix of a vessel such as arteries and veins, ducts and conduits. In Rawlings et al., an outer layer of the tissue is not removed from the jacket tissue, and there is no indication in Rawlings et al. that the extraction process thins the vessel to result in a thinned layer of tissue. Brendel et al. (4,801,299) incorporated by reference in Rawlings et al. does not disclose or suggest thinning a vessel such as an artery or vein by removal of an outer layer of the vessel tissue. Moreover, claim 43 requires a cut surface formed by removal of the outer layer of tissue by a method selected from the group consisting of peeling and shaving.

Applicant has preliminarily amended claim 29 to call for an expandable jacketed stent and a jacket formed of tissue on an outer surface of the stent in a wrapped configuration configured to unwrap as the stent expands. In the '034 application, the Examiner rejected claim 31 calling for a jacket in a wrapped configuration configured to unwrap as the sent expands, as anticipated by Love (WO 97/24081, stating that the overlapping layers of tissue of Love, when unattached, allow expansion to the larger size. However, Love discloses that the overlapped layers of tissue are held together by various means including the tubular support frame, adhesives, laser welding and suturing (page 12, lines 6-20). Love discloses that the leakage from the tubular tissue is prevented by overlapping the adjacent edges (page 12, lines 1-2). Thus, Love does not disclose or suggest a jacket configured to unwrap as the stent expands.

Applicant submits that the pending claims define patentable subject matter, and respectfully requests consideration and an early allowance thereof.

Respectfully submitted,

By: _____
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NON-THROMBOGENIC STENT JACKET

RELATED APPLICATIONS

This application is a continuation-in-part application of application Serial No. 08/935,784, filed September 23, 1997, entitled STENT COVERED WITH HETEROLOGOUS TISSUE, and application Serial No. 09/005,972, filed January 12, 1998, entitled STENT WITH A BIOCOMPATIBLE NON-THROMBOGENIC JACKET, and application Serial No. 09/035,114, filed March 4, 1998, entitled NON-THROMBOGENIC STENT JACKET CONTAINING THERAPEUTIC AGENTS, and application Serial No. 09/053,200, filed April 1, 1998, entitled NON-THROMBOGENIC STENT JACKET, which are incorporated herein in their entirety.

BACKGROUND OF THE INVENTION

This invention relates to the field of expandable intraluminal support devices such as stents and the like. Typically, stents are expandable, tubular metallic devices that are positioned within a patient's vasculature or other body lumen and expanded in order to support a vessel or body lumen at a desired intraluminal location to allow the flow of blood or other body fluids therethrough. Often, the stents are formed from a deformable metal and delivered to the desired intraluminal location by mounting the stent onto an expandable portion, e.g. a balloon, on the distal extremity of a delivery catheter. By advancing the catheter through the body lumen, the stent may

be delivered to a desired position and expanded therein by expanding the expandable member, e.g. the balloon to an expanded configuration, seating it within the artery or other body lumen. Other implementations make use of a self-expanding stent formed from a suitable material such as pseudoelastic material that is delivered in a constricted condition and when released spontaneously expands to an enlarged configuration. In other embodiments, a stent made of shape memory alloy (e.g. NiTi alloy) may be inserted into the body lumen in a martensitic phase and transformed to an austenite phase which has an expanded memory when raised to a temperature above the transformation temperature, usually less than 45°C.

Stents are often used in conjunction with an intravascular treatment for obstructive coronary artery disease. For example, ablation, atherectomy, balloon dilation, laser treatment or other procedures are among the methods used to widen a stenotic region of a patient's vasculature. However, restenosis occurs in large percentage of percutaneous transluminal coronary angioplasty (PTCA) patients and rates can be even higher with other procedures. The prior art has employed a number of mechanical and pharmacological strategies to reduce the restenosis rate, but none have been particularly effective. Accordingly, stents have been proposed to maintain the patency of a treated vessel and prevent restenosis. Using stents, restenosis rates have fallen to less than 20%.

Restenosis is thought to be a natural healing reaction provoked by injury from the intravascular procedure. The healing process frequently causes thrombosis and may lead to intimal hyperplasia that occludes the vessel. Although helpful in reducing restenosis, stents do not represent a complete solution. The framework of the stent may still allow migration and proliferation of the smooth muscle cells, while the stent itself can be thrombogenic. To address these problems, stents have been covered with DACRON, PTFE and autologous vein and the stent surface has been seeded with endothelial cells or otherwise treated. Each of these solutions suffer from certain drawbacks, such as not being biocompatible, lacking sufficient mechanical strength, having a surface that is difficult to prepare, lack of ready availability and being thrombogenic. Antithrombotic drug regimens, in which anticoagulants and thrombolytic agents are administered during and after deployment of the stent, have also been employed to reduce the risk of thrombosis.

Thus, there remains a need for a stent capable of minimizing restenosis while having a consistency similar to the native artery, a non-thrombogenic surface and sufficient mechanical strength as well as being biocompatible and readily available. This invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The invention is directed to a stent assembly suitable for maintaining the patency of a bodily lumen, generally comprising an expandable stent and an expandable, biocompatible, non-thrombogenic jacket such as heterologous tissue disposed about the exterior of the expandable stent. Preferably, the heterologous tissue is selected from the group consisting of bovine pericardium, porcine pericardium, aortic leaflet and other suitable heterologous tissue. The stent may be an expandable, tubular framework and may be a conventional self expanding or balloon expandable stent. The jacket is disposed about either or both of the outer and inner surfaces of the stent. In a preferred embodiment, the jacket is generally cylindrical for corresponding to the tubular framework or the stent.

This invention is also directed to a method for maintaining the patency of a bodily lumen generally comprising providing a delivery catheter having an expandable member on the distal extremity thereof, mounting the stent assembly, including a tubular stent with a jacket of biocompatible, non-thrombogenic expandable material such as heterologous tissue disposed about at least part of the stent, on the expandable member on the distal extremity of the delivery catheter. The catheter is advanced through the body lumen within the patient until the distal extremity of the catheter having the stent assembly is positioned at a desired location therein. The stent assembly is expanded by expanding the expandable member onto which the stent assembly is mounted to anchor the stent assembly within

the body lumen. Once the stent assembly is effectively positioned within the body lumen, the expanded expandable member may be contracted, e.g. by deflating the balloon, and then the delivery catheter may be withdrawn.

A presently preferred embodiment of the invention is directed to a stent assembly suitable for expansion within a body lumen and delivery of a therapeutic or diagnostic agent therein, generally comprising an expandable stent and an expandable, biocompatible, non-thrombogenic jacket such as heterologous tissue, which contains the therapeutic or diagnostic agent and which is disposed about the expandable stent. The jacket releasably contains at least one therapeutic or diagnostic agent.

A wide variety of therapeutic or diagnostic agents for a variety of indications can be used, including angiogenesis agents and antithrombotic agents. The term "antithrombotic agents" is meant to include various agents for reducing the risk of thrombosis, including anticoagulants such as heparin, thrombolytic agents such as urokinase, streptokinase, tissue plasminogen activator (ACTILYSE), monoclonal antibodies such as abciximab (REOPRO), fibrinolytic agents, and the like. Angiogenesis agents that stimulate the growth of neo-vessels include agents such as basic Fibroblast Growth Factor (bFGF) and Vascular Endothelial Growth Factor (VEGF).

In a presently preferred embodiment, the jacket is impregnated with a liquid containing the therapeutic or diagnostic agent. For example, a jacket formed from heterologous tissue which is submerged in a solution of the

therapeutic agent will absorb the solution. A variety of suitable methods of applying the agent to the jacket may be used, including using electrodeposition, heat and pressure. Thereafter, the stent assembly can be positioned at a desired site within the patient's body lumen, where the jacket will release the therapeutic agent. The jacket on the stent assembly may be impregnated just before use, or alternatively, stored in the therapeutic or diagnostic agent so that the stent assembly is preimpregnated.

The invention is also directed to a method for delivery of a therapeutic or diagnostic agent within a body lumen. The stent assembly including a tubular stent with a jacket of biocompatible, non-thrombogenic expandable material, such as heterologous tissue, containing a therapeutic or diagnostic agent is positioned within the body lumen as outlined above. With the stent assembly positioned at a desired location, the therapeutic or diagnostic agent is released from the jacket into the body lumen and thereby delivered at and around the location of the stent assembly within the body lumen.

The expanded jacket of biocompatible, non-thrombogenic expandable material such as heterologous tissue should extend over a substantial portion, preferably all, of the stenotic region in which it is disposed in order to minimize the restenosis.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view, partially broken away, of a stent assembly of the invention showing a tubular, expandable stent with an expandable biocompatible non-thrombogenic cylindrical exterior jacket.

Figure 2 is an elevational view, partially in section, of a delivery catheter having a jacketed stent mounted on an inflatable balloon on the distal extremity of the catheter.

Figure 3 is a transverse cross sectional view of the stent assembly shown in Figure 1, taken along lines 3-3.

Figure 4 is a perspective view, partially in section, of one embodiment of the stent assembly, shown in the expanded configuration, having a biocompatible non-thrombogenic jacket covering the length of the expandable stent.

Figure 5 is a transverse cross sectional view of one embodiment of the stent assembly prior to being expanded, illustrating the biocompatible non-thrombogenic jacket in a S-shaped folded configuration.

Figure 6 is a transverse cross sectional view of another embodiment of the stent assembly prior to being expanded, illustrating the biocompatible non-thrombogenic jacket in a U-shaped folded configuration.

Figure 7 is a perspective view, partially broken away, of one embodiment of the stent assembly having a biocompatible non-thrombogenic jacket comprising an overlapping ribbon.

Figure 8 is transverse cross sectional view of one embodiment of the stent assembly prior to being expanded, having a biocompatible non-thrombogenic jacket in an overlapping wrapped configuration.

DETAILED DESCRIPTION OF THE INVENTION

In the embodiment of the invention shown in Fig. 1, stent assembly 10 comprises a tubular, expandable metallic framework forming the stent 12 with an exterior jacket 14 of heterologous tissue. In the embodiment illustrated in Figure 1, metallic stent 12 extends about 1 mm beyond each end of jacket 14 to prevent prolapse of the tissue into the lumen of the stent when it is expanded. Jacket 14 may be secured to metallic framework 12 by any suitable means. For example, four radially spaced sutures 16 may be placed at each end of jacket 14.

In a presently preferred embodiment of the stent assembly illustrated in Fig. 1, the jacket 14 contains a therapeutic or diagnostic agent, as shown in Fig. 3, illustrating a transverse cross section of the stent assembly shown in Fig. 1, taken along lines, 3-3.

Exterior jacket 14 preferably comprises bovine pericardium, a material shown to resist suture line bleeding, require no pre-clotting, support endothelialization and have an excellent host-tissue response. Further, bovine pericardial tissue has an elasticity of up to about 30% which allows the tissue cylinder to conform to both the unexpanded and expanded

configurations of the stent 12 with out adding a great deal of bulk which increases the profile on the balloon. Other heterologous tissue suitable in the practice of the invention includes porcine pericardium, aortic leaflet, veins and arteries, and others. Useful heterologous tissue is relatively impervious and impenetrable so as to prevent tissue build up and the migration of smooth muscle cells through the stent framework. A particularly preferred bovine pericardium has cross-linked collagen and is available from Bio Vascular. Bovine pericardium tissue is available in a thickness ranging from about 0.25 mm to about 0.75 mm, with an average of about 0.45 mm.

In a presently preferred embodiment of the invention, the biocompatible non-thrombogenic jacket 14 has a thickness of less than about 0.25 mm, and preferably has a thickness of about 0.05 mm to about 0.20 mm, and most preferably about 0.1 mm to about 0.15 mm. However, biocompatible non-thrombogenic jackets having a thickness of up to about 0.75 mm may be used. In the embodiment of the invention in which a thin biocompatible non-thrombogenic jacket having a thickness of less than about 0.25 mm is used, the heterologous tissue used to form the jacket is typically thinned before being assembled with the stent. The tissue may be thinned by a variety of suitable methods including peeling, shaving or otherwise removing a thin layer of the tissue. In a presently preferred embodiment, the thin jacket comprises the serous pericardium, which is the smooth, inner layer of the pericardium, which has been separated from at least a part of the

outer layer of the pericardium. Similarly, where other forms of heterologous tissue are used, such as veins or arteries, the venous or arterial walls may be thinned to the presently preferred thickness of about 0.05 mm to about 0.20 mm. As a result of being thinned, the jacket may have reduced elasticity, so that the thin jacket is preferably provided on the unexpanded stent in a folded or overlapping wrapped configuration which provides sufficient material to cover the larger circumference of the expanded stent, as will be discussed in greater detail below.

The biocompatible non-thrombogenic jacket 14 preferably has a length configured to cover the length of the expanded stent, as illustrated in Fig. 4, showing an expanded stent 12 with a jacket 14 extending the length of the stent, with a length equal to the stent length. However, the jacket may have a length that is not equal to the length of the stent. For example, the jacket may have a length less than the stent length, as illustrated in Fig. 1, preferably not more than about 10%-20% less than the length of the stent. However, the jacket may cover an even smaller percentage of the length of the stent, as for example, when the stent assembly is used in a Transjugular Intrahepatic Portal Shunt (TIPS) application, where the jacket length is about 50% less than the length of the stent. Alternatively, the jacket may have a length greater than the length of the stent, preferably not more than about 5% greater than the stent length. The jacket preferably has a circumference about equal to the circumference of the expanded stent, configured to fit on

an inner or outer surface of the expanded stent. The jacket preferably fits on the expanded stent so that the jacket conforms to the expanded stent without flaps of excess material.

Metallic stent 12 may comprise any suitable conventional stent. For example, Micro Stent II and GFX stents available from Arterial Vascular Engineering, and Multi-Link, available from Guidant, have proven useful. Other stents that may be used in the practice of this invention include the Palmaz-Shatz stent from Johnson and Johnson, the Gianturco stent from Cook Incorporated and other commercially available stents. Conventional balloon expandable stents are preferred, but, as previously mentioned, self-expanding stents, such as those formed from shape memory materials, are also suitable.

The stent assembly is formed by covering a surface of the unexpanded stent with the heterologous tissue forming the jacket 14. In one embodiment, the heterologous tissue is mounted onto the unexpanded stent in the form of a cylinder of tissue. The cylinder of heterologous tissue forming the jacket 14, may be formed by cutting a rectangle of tissue having a length about 2 mm shorter than the stent on which it is to be mounted and a width about equal to the circumference of the expanded stent. The two sides corresponding to the length of the stent then may be secured together, such as by sewing with 6-0, 7-0, 8-0 or 10-0 polypropylene sutures. Other means for securing the sides of the stent cover together include mechanical means such as staples, adhesive or chemical bonding and the like. It may be

desirable to support the tissue while manipulating it. For example, a 9 French introducer dilator may be used to support a 3 mm diameter cylinder, an 11 French dilator for a 3.5 mm cylinder and a 12 French dilator for a 4 mm cylinder. The cylinder of tissue having a circumference about equal to the circumference of the expanded stent may be provided on the unexpanded stent in a folded or wrapped configuration. In one embodiment, the tissue on the unexpanded stent forms wings 30 on either side of the stent which are folded about stent, reducing the profile of the assembly, and unfolding upon expansion of the stent. In the embodiment illustrated in Fig. 5, the wings are folded in the same direction in an S-shaped configuration. In another embodiment, illustrated in Fig. 6, the wings of the cylinder of tissue on the unexpanded stent are folded about stent in opposite directions in a U-shaped configuration. However, the cylinder of tissue may be placed about the unexpanded stent in a variety of suitable configurations, as for example, where the wings of the cylinder of tissue are collapsed toward the stent, such as in an accordion type configuration (not shown). It would be apparent to one of skill in the art that the heterologous tissue forming the jacket could be folded about the unexpanded stent as outlined above whether or not the tissue had been formed into a cylinder of tissue before mounting onto the unexpanded stent.

In another embodiment, the heterologous tissue is wrapped around the unexpanded stent, so that sufficient tissue to cover the expanded stent is

provided. In one embodiment, illustrated in Fig. 7, a ribbon of tissue is spirally wrapped around the unexpanded stent down a length thereof. The adjacent turns of the ribbon of tissue overlap, so that the ribbon unwraps as the stent expands to provide the jacket 14 configured to cover the expanded stent and having a circumference about equal to the circumference of the expanded stent. Preferably, the ribbon of tissue is wrapped along the entire length of the stent. In another embodiment, a rectangle of tissue having a width about equal to the circumference of the expanded stent on which it is to be mounted is repeatably wrapped around the outer circumference of the unexpanded stent, so that multiple layers of tissue are present on at least a part of the unexpanded stent, as shown in Fig. 8, illustrating a transverse cross section of an unexpanded stent with a wrapped jacket thereon. Preferably, one end of the tissue is fixed to the stent, and the tissue is then tightly wrapped around the stent. Upon expansion of the stent, the tissue unwraps to provide the jacket 14 having a circumference about equal to the circumference of the expanded stent. Preferably the length of the tissue is about equal to the length of the stent.

The tissue can be caused to remain in the folded or wrapped configurations until the stent is expanded by pressing the fluid out of the folded or wrapped tissue. Additionally, securing members such as surgical tape, ties, or breakable bands may be provided to releasably hold the tissue in the folded or wrapped configurations.

Depending upon the jacket material, the tissue may be kept wet at all times during manipulation or it may be dry until advanced into the patient's blood stream. Additionally, radio-opaque markers, such as rings of gold or platinum, may be added to the outer layer of the tissue so that the integrity of the cylinder may be assured before deployment within the body lumen. The cylinder of heterologous tissue configured to be mounted onto a stent and the jacket 14 formed by the cylinder of tissue or the unwrapped or unfolded tissue generally has a length, for coronary applications, of about 4 to greater than about 80 mm, typically about 5 to about 80 mm, preferably about 10 to about 50 mm, and a diameter of about 1.5 to about 35 mm, typically about 2 to about 6 mm, preferably about 2.5 to about 5 mm. The actual length and diameter of the cylinder of heterologous tissue may vary, and will depend on the nature of the vessel in which the stent assembly is implanted. For example, for peripheral vessel applications, such as an aortic abdominal aneurysm, a larger cylinder of heterologous tissue having a length of about 5 mm to about 200 mm and a diameter of about 2 mm to about 60 mm would be used.

The jacketed stent assembly 10 is inserted into the body lumen in the following fashion. A guidewire 20 is backloaded into a delivery catheter 22 having the jacketed stent assembly 10 mounted over an inflatable balloon 24 on the distal extremity of the delivery catheter (as schematically shown in Fig. 2) or on a self expanding stent delivery system (not shown). The

catheter 22 and guidewire 20 are percutaneously introduced by means of a conventional Seldinger technique and a 5-9 or 10 French guiding catheter (not shown) into the patient's arterial system. Larger guiding catheters, for example up to about 25 Fr, may be used depending on the application. The guidewire 20 is advanced out delivery catheter 22 through the vasculature under fluoroscopic imaging until it crosses a stenotic region. Then the catheter 22 is advanced over the guidewire 20 until the stent assembly 10 is positioned at the desired location within the stenotic region. Then, the balloon 24 is inflated or the securing mechanism of the self expanding stent is released to expand the stent 12 and cylindrical jacket 14, seating the assembly 10 within the vessel. The balloon 24 is then deflated and the catheter 22 is removed, leaving the expanded stent assembly 10 in place.

Although primarily described with respect to preventing restenosis in angioplasty patients, the covered stents of this invention may be used in a number of coronary artery, peripheral artery and non-vascular applications. For example, coronary artery applications include use in ectatic arteries and ectatic arteries containing an obstructive lesion, aneurismatic arteries, saphenous vein grafts and native arteries, coronary perforation, coronary fistula, and ostial coronary lesions. Peripheral artery applications include aortic abdominal aneurysm and other aneurismatic peripheral arteries, transjugular intrahepatic portal shunt, percutaneous transluminal angioplasty, fistula closing and neuro interventions (such as aneurysms and arterial-

venous malformations), small vessel intraluminal grafting, and ostial renal artery lesions. Finally, the covered stents of this invention may be used in urological, gastroenterological, respiratory, neurological, and other non-vascular applications. For example, urological field applications include urethral stenting for stenosis due to tumors, fibrous tissue and perforation. Gastroenterological field applications include fistula closing, reconstruction such as esophagus reconstruction, and esophageal bleeding. Respiratory field applications include tracheal and bronchial obstructions, and neurological field applications include carotid angioplasty.

A general description of the device of the present invention as well as a preferred embodiment of the present invention has been set forth above. One skilled in the art will recognize and be able to practice many changes in many aspects of the device described above, including variations that fall within the teachings of this invention. For example, the assembly may include a second expandable stent, so that the heterologous tissue layer is between two coaxially disposed stents. Additionally, the jacket may cover the entire stent or only a portion thereof. Additionally, the stent assembly may be used in branched body lumens, and positioned to block one or more of the branch lumens. The spirit and scope of the invention should be limited only as set forth in the claims which follow.

WHAT IS CLAIMED IS:

1. A stent assembly for maintaining the patency of a body lumen comprising an expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic material.

2. The stent assembly of claim 1 wherein the cylindrical jacket is formed of heterologous tissue.

3. The stent of claim 2, wherein the heterologous tissue is selected from the group consisting of bovine pericardium, porcine pericardium, and aortic leaflet, veins and arteries.

4. The stent of claim 3, wherein the heterologous tissue comprises bovine pericardium with cross-linked collagen.

5. The stent of claim 2 including at least one therapeutic or diagnostic agent releasably contained in the cylindrical jacket.

6. The stent assembly of claim 1 wherein the material is expandable.

7. The stent assembly of claim 1 wherein the stent comprises a metallic tubular member.

8. The stent assembly of claim 1 wherein the cylindrical jacket is on an exterior surface of the stent.

9. The stent assembly of claim 1 wherein the stent is disposed within the cylindrical jacket.

10. A method for maintaining the patency of a body lumen comprising the steps of:

a) mounting on a delivery catheter a stent assembly comprising a tubular expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic expandable material;

b) advancing the delivery catheter through the body lumen until the stent assembly is positioned at a desired location;

c) expanding the stent assembly to anchor it within the bodily lumen; and

d) withdrawing the delivery catheter.

11. A cylindrical jacket formed of heterologous tissue configured to fit over a portion of an intraluminal stent.

12. The cylindrical jacket of claim 11 having a length of about 4 to about 200 mm.

13. The cylindrical jacket of claim 11 having a length of about 10 to about 50 mm.

14. The cylindrical jacket of claim 11 having a diameter of about 1.5 to about 60 mm.

15. The cylindrical jacket of claim 14 having a diameter of not greater than about 6 mm.

16. The cylindrical jacket of claim 11 having a diameter of about 2.5 to about 5 mm.

17. The cylindrical jacket of claim 11 having a thickness of about 0.05 mm to about 0.20 mm.

18. The cylindrical jacket of claim 11 having a thickness of about 0.1 mm to about 0.15 mm.

19. The cylindrical jacket of claim 11 configured to fit over an outer portion of the intraluminal stent.

20. The cylindrical jacket of claim 11 configured to cover an inner portion of the intraluminal stent.

21. A method of treating a patient, comprising:

a) providing an elongated delivery catheter having an expandable member on a distal extremity thereof;

b) mounting an expandable stent having a cylindrical jacket formed of biocompatible, non-thrombogenic expandable material onto the expandable member on the distal extremity of the delivery catheter;

c) advancing at least the distal extremity of the catheter within a body lumen of the patient until the jacketed stent is disposed at a desired location within the body lumen;

d) expanding the expandable member on the distal extremity of the catheter to expand the jacketed stent mounted thereon and fix the expanded jacketed stent within the body lumen; and

e) contracting the expanded expandable member so the elongated delivery catheter can be removed from the patient.

22. A stent assembly for maintaining the patency of a body lumen comprising an expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic expandable material containing a therapeutic or diagnostic agent.

23. The stent assembly of claim 22 wherein the therapeutic agent is selected from the group consisting of antithrombotic agents and angiogenesis agents.

24. The stent assembly of claim 23 wherein the antithrombotic agent is selected from the group consisting of is selected from the group consisting of heparin, urokinase, streptokinase, tissue plasminogen activator, and abciximab, and the angiogenesis agent is selected from the group consisting of Fibroblast Growth Factor and Vascular Endothelial Growth Factor.

25. The stent assembly of claim 22 wherein material comprises heterologous tissue configured to fit over at least one of an outer surface and an inner surface of the stent.

26. A method for maintaining the patency of a body lumen comprising the steps of:

a) mounting on a delivery catheter a stent assembly comprising a tubular expandable stent with a cylindrical jacket formed of biocompatible, non-thrombogenic expandable material containing a therapeutic or diagnostic agent;

b) advancing the delivery catheter through the body lumen until the stent assembly is positioned at a desired location;

c) expanding the stent assembly to anchor it within the bodily lumen and deliver the therapeutic or diagnostic agent to the desired location within the body lumen; and

d) withdrawing the delivery catheter.

27. The method of claim 26 wherein the delivery catheter has an expandable member on a distal extremity thereof, and including the step of mounting the expandable stent onto the delivery catheter expandable member, and wherein the step of expanding the stent comprises expanding the delivery catheter expandable member.

28. The method of claim 26 including the step of contracting the expanded expandable member so the delivery catheter can be removed from the patient.

29. An expandable jacketed stent comprising a metallic tubular member configured to expand from a first circumference configuration to a second circumference configuration, and a jacket formed of heterologous tissue containing a therapeutic or diagnostic agent and having a thickness of about 0.05 mm to about 0.20 mm.

30. The jacketed stent of claim 29 wherein the jacket is on an outer surface of the stent in a folded configuration configured to unfold as the stent expands to the second circumference configuration.

31. The jacketed stent of claim 29 wherein the jacket is on an outer surface of the stent in a wrapped configuration configured to unwrap as the stent expands to the second circumference configuration.

32. A method of treating a patient, comprising:

a) providing an elongated delivery catheter having an expandable member on a distal extremity thereof;

b) mounting onto the expandable member on the distal extremity of the delivery catheter an expandable stent having first circumference and a second expanded circumference and having a

cylindrical jacket formed of biocompatible, non-thrombogenic expandable material on an outer surface of the stent, the jacket having a width about equal to the second expanded circumference of the stent;

c) advancing at least the distal extremity of the catheter within a body lumen of the patient until the jacketed stent is disposed at a desired location within the body lumen;

d) expanding the expandable member on the distal extremity of the catheter to expand the jacketed stent mounted thereon and fix the expanded jacketed stent within the body lumen; and

e) contracting the expanded expandable member so the elongated delivery catheter can be removed from the patient.

33. The method of claim 32 wherein the jacket is in a folded configuration configured to unfold as the stent expands to the second circumference configuration.

34. The method of claim 32 wherein the jacket is in a wrapped configuration configured to unwrap as the stent expands to the second circumference configuration.

ABSTRACT OF THE DISCLOSURE

A jacketed stent assembly comprising a tubular, expandable stent, preferably having a metallic framework, jacketed with a cylinder of biocompatible, non-thrombogenic expandable material, such as heterologous tissue, which, in a preferred embodiment, contains a therapeutic or diagnostic agent. In a preferred embodiment, the jacket of the expandable stent is formed of bovine or porcine pericardial tissue. A delivery catheter having an expandable member on its distal extremity may be used to deliver the stent assembly to a desired region in a lumen of a patient. The jacketed stent is expanded to be seated within the body lumen. Self-expanding jacketed stents are also contemplated

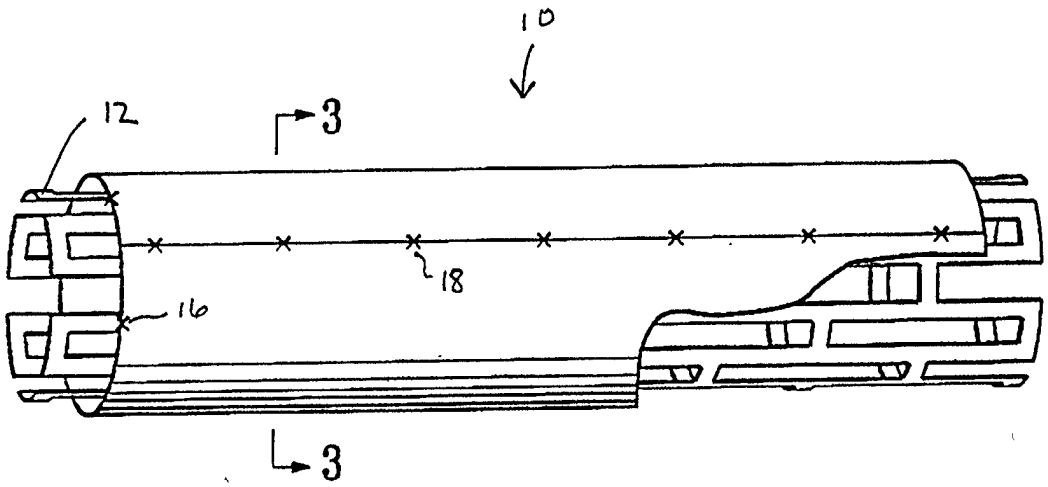

FIG. 1

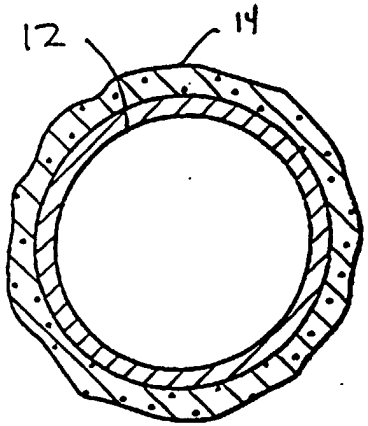

FIG. 3

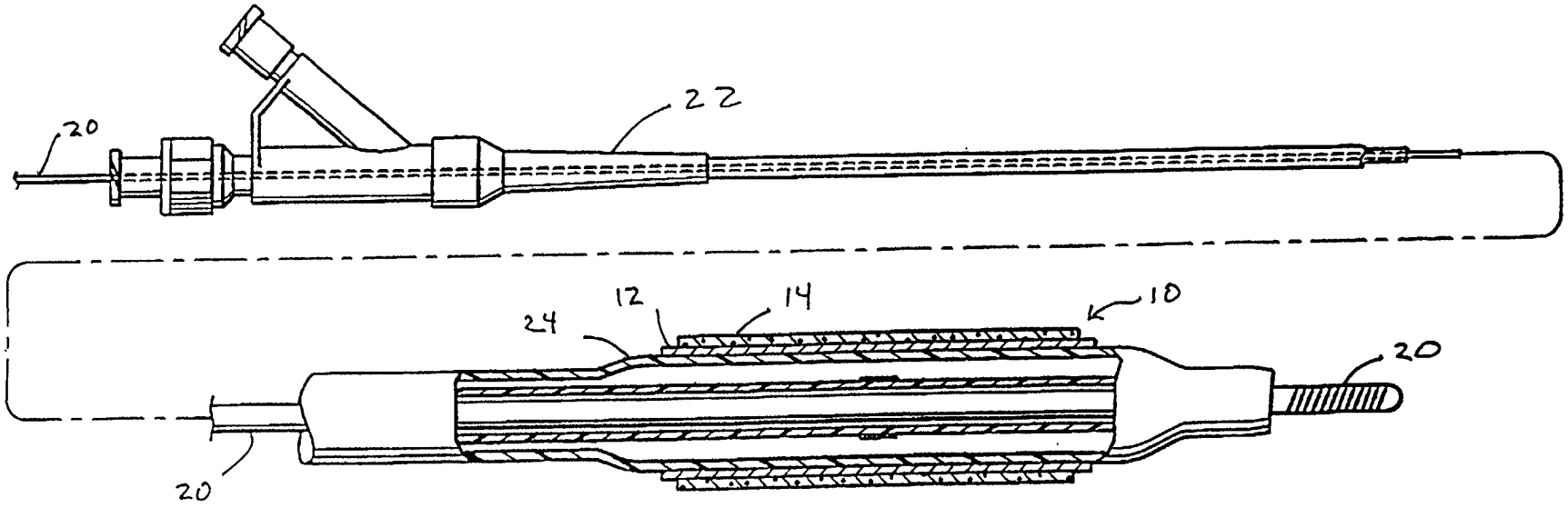

FIG. 2

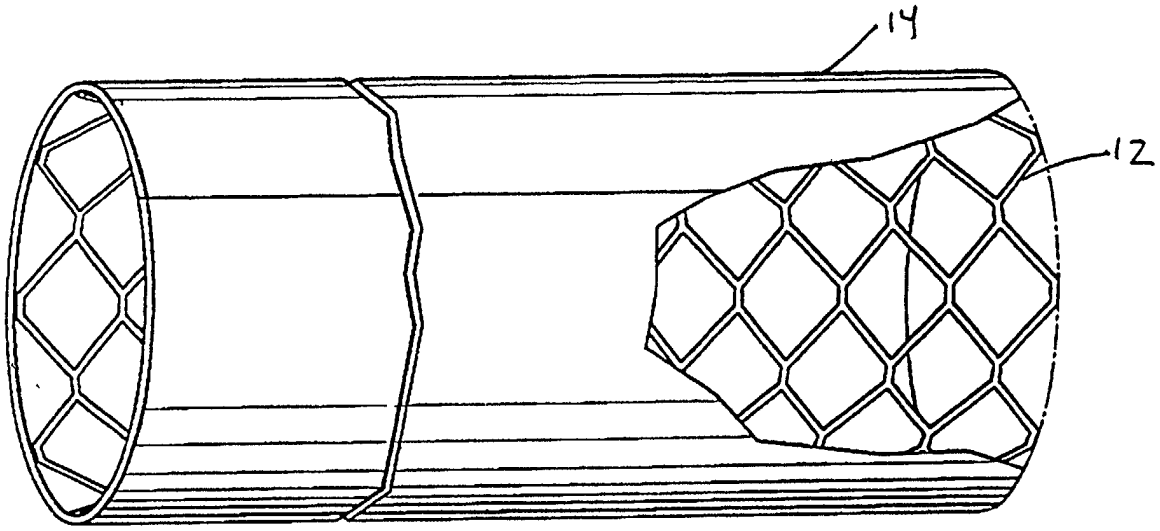

FIG. 4

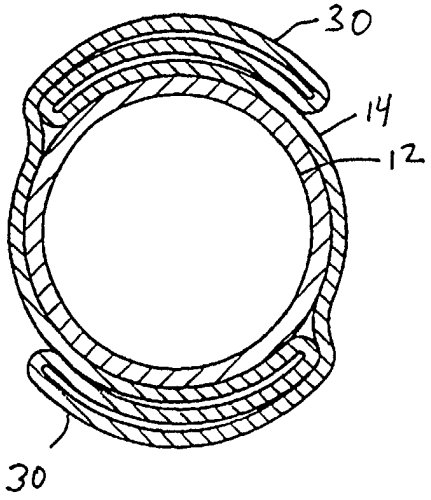

FIG. 5

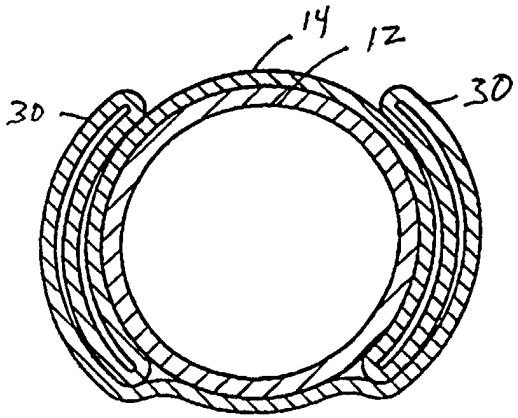

FIG. 6

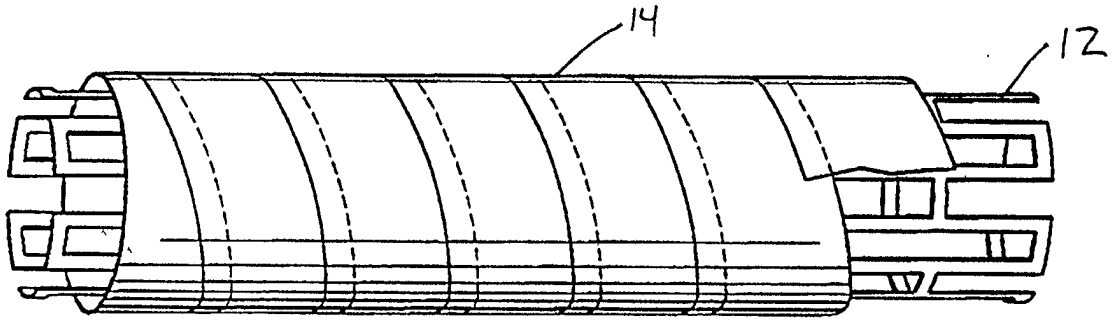

FIG. 7

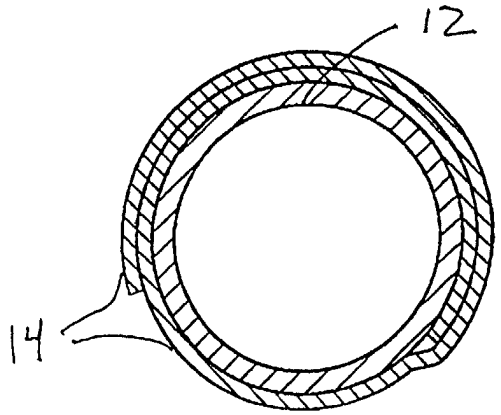

FIG. 8

L :LARATION AND POWER OF ATTO. EY

As the below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled, **NON-THROMBOGENIC STENT JACKET**, for which a specification was submitted to the United States Patent and Trademark Office for filing on September 17, 1998, and assigned application Serial No. 09/156,034.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by or any amendment(s) referred to above.

This application in part discloses and claims subject matter disclosed in my earlier filed pending application Serial Nos. 08/935,784, filed September 23, 1997, 09/005,972, filed January 12, 1998, 09/035,114, filed March 4, 1998, and 09/053,200, filed April 1, 1998.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, we acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

08/935,784, filed September 23, 1997	09/035,114, filed March 4, 1998
09/005,972, filed January 12, 1998	09/053,200, filed April 1, 1998

I hereby declare under penalty of perjury under the laws of the United States of America that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following attorneys to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith:

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Executed on 5 day of January, 1999.

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